

their particular AWP-inflated drugs and their market share for those drugs,” AMCC ¶ 5. These cursory, theoretical allegations do not come close to satisfying Rule 9(b).

First, there is not a single allegation in the AMCC about any statement that any defendant made to any PBM. Nor are there any allegations about how any particular defendant “marketed the spread” to any particular PBM; there is only general speculation that defendants must have “marketed the spread” to PBMs because defendants allegedly did so in connection with certain Medicare drugs. Such generalized allegations about “all defendants” are plainly insufficient under Rule 9(b). *See, e.g., Luce v. Edelstein*, 802 F.2d 49, 54 (2d Cir. 1986); *Center Cadillac, Inc. v. Bank Leumi Trust Co.*, 808 F. Supp. 213, 230 (S.D.N.Y. 1992) (“A complaint sounding in fraud may not rely on sweeping references to acts by all or some of the defendants because each named defendant is entitled to be apprised of the facts surrounding the alleged fraud.”).

Second, the plaintiffs never identify a particular drug involved in this alleged PBM fraud. In paragraph 178 of the AMCC, there is a citation to a *Wall Street Journal* article about how the PBM Express Scripts allegedly profited from the drug floxetine, but no manufacturer is identified and there is no allegation that any defendant marketed the spread on this particular drug. In any event, this is the only allegation provided to support plaintiffs’ PBM theory. Accordingly, plaintiffs’ PBM claims must be dismissed pursuant to Rule 9(b).

**B. Plaintiffs Fail To Allege A “Fraudulent AWP” For The Vast Majority Of The Drugs Named In The AMCC.**

Plaintiffs fail to plead a “fraudulent AWP” for each drug at issue, as this Court required. *AWP Litigation*, 263 F. Supp. 2d at 194. This failure requires the dismissal of all claims premised on plaintiffs’ PBM theory. In addition, plaintiffs fail to satisfy Rule 9(b) with respect to those Medicare Part B drugs for which there are no particularized allegations.

In the PBM context, plaintiffs contend that they paid fraudulent prices for defendants' drugs. AMCC ¶ 172. Yet, remarkably, they fail to specify the allegedly fraudulent prices that they paid. In the absence of particularized allegations about the percentage discounts off AWP that plaintiffs negotiated in their arm's length transactions with PBMs, it is impossible to determine whether plaintiffs paid anything close to the published AWP that they allege is somehow fraudulent. Plaintiffs' failure to allege a single price paid by even a single plaintiff for a single drug is inexcusable. *See* Oral Arg. Tr. at 101 (admitting that plaintiffs know what they paid for the drugs at issue). *Compare Efron v. Embassy Suites (P.R.), Inc.*, 223 F.3d 12, 16 (1<sup>st</sup> Cir. 2000) (explaining that relaxation of pleading requirements where information is in defendant's sole possession does not apply where the information is held by plaintiffs).

Indeed, in response to the Court's direction, plaintiffs do no more than regurgitate the published AWP for the drugs listed in Appendix A. Plaintiffs fail to explain how these published AWP are fraudulent, except to speculate that there is a difference between these published AWP and the cost to PBMs (*i.e.*, a "spread"). *See* AMCC ¶ 161, 171. But mere speculation about a hypothetical "spread" is not sufficient to satisfy Rule 9(b) or the Court's instruction that they identify the "fraudulent AWP" for the drugs at issue in their PBM claims. According, those claims must be dismissed.

Likewise, in the Medicare Part B context, plaintiffs assert that they overpaid for "all drugs administered under Medicare Part B." AMCC ¶¶ 140, 141. Yet, the AMCC includes allegations relating to only a handful of Medicare Part B drugs. Accordingly, plaintiffs' claims relating to Medicare Part B drugs about which there are no particularized allegations must be dismissed.

**C. The Allegations Pertaining To “Other” Alleged “Hidden and Improper Inducements” Are Also Devoid Of Any Particulars.**

In a span of four short paragraphs, the plaintiffs seek to include other alleged practices as part of their claims, such as the “improper use of free samples,” AMCC ¶¶ 164-66, and “other non-public financial inducements” like “volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants,” AMCC ¶ 167. These sweeping, all-inclusive allegations, devoid of particulars as to the conduct of individual defendants, are plainly insufficient under Rule 9(b). *See, e.g., Center Cadillac*, 808 F. Supp. at 230.

In sum, plaintiffs have failed to heed the Court’s direction to abide by Rule 9(b). Since this failure comes after three chances and the opportunity to review over one million pages of documents produced by defendants, the PBM claims, the claims about drugs with no allegation of a purchaser or fraudulent AWP, and the claims relating to drug samples and other physician inducements must be dismissed with prejudice.<sup>4</sup>

**II. PLAINTIFFS’ RICO CLAIMS SHOULD BE DISMISSED.**

“‘[C]ourts should strive to flush out frivolous [civil] RICO allegations at an early stage of the litigation.’” *Bowdoin Constr. Corp. v. Rhode Island Hosp. Trust Nat’l Bank, N.A.*, 869 F. Supp. 1004, 1006 (D. Mass. 1994) (Saris, J.) (citations omitted), *aff’d sub nom., Schultz v. Rhode*

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<sup>4</sup> In addition, because plaintiffs only allege published AWPs for 1997 through 2002, at a minimum, any remaining claims must be limited to this time period. Furthermore, for the reasons set forth in the individual memorandum of the Bristol Meyers Squibb defendants, all pre-1997 claims are barred by the applicable statute of limitations.

Moreover, plaintiffs fail to allege a purchaser for each one of the drugs they contend are at issue. A spreadsheet identifying, by manufacturer, each of the drugs identified in Appendix A of the AMCC for which no plaintiff purchaser has been identified in Appendix B is attached hereto as Exhibit A. Because no purchaser is alleged for the drugs listed in Exhibit A, claims with respect to those drugs must be dismissed.

*Island Hosp. Trust Nat'l Bank, N.A.*, 94 F.3d 721 (1<sup>st</sup> Cir. 1996). Accordingly, “while ‘the pleadings should generally be construed liberally. . . a greater level of specificity is required in RICO cases.’” *Divot Golf Corp. v. Citizens Bank of Mass.*, No. Civ. A. 02-CV-10654-PBS, 2002 WL 31741472, at \*1 (D. Mass. Nov. 26, 2002) (Saris, J.) (*quoting Bessette v. Avco Fin. Servs., Inc.*, 230 F.3d 439, 443 (1<sup>st</sup> Cir. 2000)).<sup>5</sup>

These admonitions are particularly appropriate here. Plaintiffs have provided more pages, paragraphs, and enterprises, but they have not provided more facts. Rather, they merely repeat conclusory, boilerplate assertions that parrot the RICO statute and the Court’s Order. Instead of curing the defects in their original RICO claims, plaintiffs have multiplied them.

Under § 1962(c), plaintiffs must allege that defendants were “employed by or associated with” a RICO enterprise, and that defendants engaged in the (1) conduct (2) of the enterprise (3) through a pattern (4) of racketeering activity. 18 U.S.C. § 1962(c); *Sedima S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). In addition, plaintiffs also must satisfy the proximate cause element. 18 U.S.C. § 1964(c). To withstand a motion to dismiss, “[i]t is not enough. . . for a plaintiff simply to allege the above elements in boilerplate fashion; instead, [plaintiff] must allege sufficient facts to support each element.” *Goren v. New Vision Int’l, Inc.*, 156 F.3d 721, 727 (7<sup>th</sup> Cir. 1998); *see also Jennings, D.C. v. Emry*, 910 F.2d 1434, 1435 (7<sup>th</sup> Cir. 1990) (plaintiffs’ lengthy complaint failed to state a RICO claim, and its “conclusory allegations that various statutory provisions have been breached are of no consequence if unsupported by proper factual allegations”).

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<sup>5</sup> *See also Farlow v. Peat, Marwick, Mitchell & Co.*, 956 F.2d 982, 989 (10<sup>th</sup> Cir. 1992) (“Under Rule 9(b), plaintiffs must sufficiently allege each element of a RICO violation and its predicate acts of racketeering with particularity . . .”).

Plaintiffs have failed to allege the necessary elements of a RICO claim under any pleading standard. In particular, plaintiffs fail to set forth a single viable RICO enterprise, fail to demonstrate that defendants conducted or participated in the affairs of the alleged enterprises, and fail to allege causation of harm by any conduct of defendants.

**A. Plaintiffs Do Not Allege A Viable RICO Enterprise.**

In the MCC, plaintiffs attempted to construct a viable RICO claim through an array of alternative theories encompassing 79 different alleged enterprises. The Court rejected this effort.<sup>6</sup> Rather than presenting a more streamlined theory, plaintiffs' AMCC is even broader and more complicated than its predecessor. The 79 alternate enterprises have been replaced by 154, a task achieved by taking "enterprises" that the Court already has rejected and breaking them up into numerous "mini-enterprises."

In Count I, plaintiffs set forth a series of "Manufacturer-Publisher Enterprises," which are alleged to be "associations-in-fact consisting of (a) one of the Publishers that reported AWP for AWPIDs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents." AMCC ¶ 624.<sup>7</sup> Count II similarly sets forth a series of "Manufacturer-PBM RICO Enterprises," alleged to be "associations-in-fact consisting of (a) one of the PBMs that administered purchases of a Defendant Drug Manufacturer's brand name drugs and billed its members on the basis of the Defendant Drug Manufacturer's reported AWP, and (b) a

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<sup>6</sup> Because the Court dismissed the RICO counts in the MCC for failure to allege an enterprise, it did not reach the other deficiencies in those claims. *See AWP Litigation*, 263 F. Supp. 2d at 181 n.9.

<sup>7</sup> The plaintiffs have identified the following publishers: Thomson Medical Economics; First Data Bank, Inc.; and Facts & Comparisons, Inc. AMCC ¶ 622. Each of 22 defendants is alleged to have entered into a separate association-in-fact enterprise with each of these three publishers.

defendant Drug Manufacturer, including its directors, employees and agents.” AMCC ¶ 651.<sup>8</sup>

These alleged enterprises are merely variations of the “Publisher Enterprises” and “PBM Enterprises” set forth in the MCC. *Compare* MCC ¶¶ 370-77 and MCC ¶¶ 429-31 with AMCC ¶¶ 619-28 and AMCC ¶¶ 651-61. In the AMCC, plaintiffs have simply disaggregated the enterprises alleged in the MCC, so that each defendant is now alleged to have engaged in separate enterprises with each publisher and each PBM. They have done so in an effort to avoid this Court’s finding that the enterprises in the MCC had a “hub-and-spoke design,” *AWP Litigation*, 263 F. Supp. 2d at 183, which lacked a “rim to connect the spokes,” *id.* at 184. However, even if plaintiffs have avoided the “hub-and-spoke” analogy, they have not cured the other deficiencies in the enterprise allegations that were fatal to their original RICO claims.

To establish an association-in-fact enterprise, the plaintiff must plead facts demonstrating the existence of an “entity separate and apart from the pattern of racketeering activity in which it engages.” *United States v. Turkette*, 452 U.S. 576, 583 (1981). This requires evidence of “an ongoing organization” whose members “function as a continuing unit” and are “associated together for a common purpose of engaging in a course of conduct.” *Id.*; *see also AWP Litigation*, 263 F. Supp. 2d at 182 (holding that a plaintiff must demonstrate that the associated groups “constitute a larger unit, over and above their separate structures and operations.”) (quoting *Libertad v. Welch*, 53 F.3d 428, 442 (1<sup>st</sup> Cir. 1995)). Moreover, these enterprise allegations must be pled with the heightened specificity required by Rule 9(b).<sup>9</sup>

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<sup>8</sup> The AMCC identifies four PBMs: AdvancePCS; Caremark, Rx, Inc.; Express Scripts, Inc.; and Medco Health Solutions, Inc. AMCC ¶ 650. Each of 22 drug manufacturers is alleged to have entered into a separate association-in-fact enterprise with each of these four PBMs.

<sup>9</sup> *See, e.g., Brooks v. Bank of Boulder*, 891 F. Supp. 1469, 1476 (D. Colo. 1995) (RICO enterprise must be pled with particularity under Rule 9(b)); *O&G Carriers, Inc. v. Smith*, 799 F. Supp. 1528, 1540-42 (S.D.N.Y. 1992) (same); *Miller Hydro Group v. Popovitch*, 793 F. Supp. 24, 28 (D. Me. 1992) (same); *Plount v. Am. Home*

As this Court noted, “[t]he First Circuit has considered several factors in determining whether a RICO association-in-fact enterprise has been properly asserted:

(1) whether the associates have a common purpose; (2) whether there is “systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination”; (3) whether there is a common communication network for sharing information on a regular basis; (5) whether the associates hold meetings and sessions where important discussions take place; (6) whether the associates wear common colors, signs or insignia to make the group identifiable; and (7) whether the group conducted common training and instruction.

*AWP Litigation*, 263 F. Supp. 2d at 182 (citations omitted).

In the AMCC, plaintiffs lift this language from the Court’s Order, and repeat it over and over, mantra-like, in an attempt to state viable enterprises. However, they fail to allege any facts showing that any of these factors is present here. Instead, they rely on “ritualistic averment[s], in wholly conclusory terms,” to attempt to overcome the deficiencies that were identified in the Court’s Order. *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 n.7 (1<sup>st</sup> Cir. 1991) (plaintiff-appellants failed to allege a valid enterprise where complaint “contained no allegations articulating how any of the appellees may have comprised part of an ‘ongoing organization’ or ‘function[ed] as a continuing unit’”) (citations omitted).

**1. The Manufacturer-Publisher Enterprises Are Deficient Because Plaintiffs Have Failed To Plead Facts Showing That They Constitute Ongoing Organizations Whose Members Function As Continuing Units And Share Common Purposes.**

Plaintiffs allege that each of the “Manufacturer-Publisher Enterprises” is an

ongoing and continuing business organization...[whose members] are and have been associated for the common or shared purposes of (a) publishing or otherwise

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*Assurance Co.*, 668 F. Supp. 204, 206-07 (S.D.N.Y. 1987) (same); *Slattery v. Costello*, 586 F. Supp. 162, 168 (D.D.C. 1983) (same). But see *American Buying Ins. Servs., Inc. v. S. Kornreich & Sons, Inc.*, 944 F. Supp. 240, 246-47 (S.D.N.Y. 1996) (RICO enterprise need not comply with Rule 9(b)); *Spira v. Nick*, 876 F. Supp. 553, 561 (S.D.N.Y. 1995); *Fed. Paper Bd. Co. v. Amata*, 693 F. Supp. 1376, 1395 n.31 (D. Conn. 1988); *Lingle v. Ziola*, 701 F. Supp. 158, 160 (N.D. Ill. 1988); *N. Ky. Bank & Trust v. Rhein*, 1984 WL 23248, at \*1 (E.D. Ky. Sept. 18, 1984).

disseminating pharmaceutical price information, which all too often includes disseminating false and misleading AWP, (b) selling, purchasing, and administering AWPIDs to Plaintiffs and Class members, and (c) deriving profits from these activities.

AMCC ¶ 624. They allege that “[e]ach of the enterprises had a common purpose of perpetuating use of AWP as a benchmark for reimbursement in the pharmaceutical industry, generally, and specifically for the drugs of that defendant.” *Id.* Thus, plaintiffs assert that 66 separate and distinct RICO enterprises operated in parallel and shared the identical common purpose. *See* AMCC ¶ 628. Plaintiffs also allege that each of these enterprises had a “systematic linkage,” a “common communication network,” *id.* ¶ 625, and a “hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer,” *id.* ¶ 635.<sup>10</sup>

These “ritualistic” averments fail to satisfy any of the *Turkette* requirements. First, plaintiffs do not plead facts showing the necessary “ongoing organization.” While plaintiffs state the conclusion that “each of the Manufacturer-Publisher Enterprises is an ongoing and continuing business organization,” AMCC ¶ 624, they do not plead a single fact to support it. Indeed, plaintiffs fail to allege any organizational structure beyond the promotion of the “AWP scheme.” AMCC ¶ 624. A RICO enterprise “must exhibit structural continuity which exists where there is an organizational pattern or system of authority that provides a mechanism for directing the group’s affairs on a continuing, rather than ad hoc, basis.”” *Manhattan Telecomms. Corp. v. DialAmerica Mktg., Inc.*, 156 F. Supp. 2d 376, 380-81 (S.D.N.Y. 2001) (citation omitted) (dismissing RICO claims for lack of adequate allegations that defendants and their customers functioned as a continuing unit); *see also VanDenBroeck v. CommonPoint Mortg. Co.*,

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<sup>10</sup> The allegations directed at individual defendants, rather than defendant manufacturers as a whole, represent nothing more than a recitation of the general RICO enterprise allegations, with the names of an individual drug manufacturer and the publishing companies inserted. *See* AMCC ¶ 628 (a)-(v).

210 F.3d 696, 699 (6<sup>th</sup> Cir. 2000) (citation omitted) (“the hallmark of a RICO enterprise is the ability to exist apart from the pattern of wrongdoing”).

Similarly, while plaintiffs state the conclusion that “[e]ach of the Manufacturer-Publisher Enterprises had a hierarchical decision making structure,” AMCC ¶ 635, they do not plead a single fact describing that structure. In fact, the AMCC itself reveals the lack of any such structure. On the face of the AMCC, the “structure” of the alleged Manufacturer-Publisher Enterprises is simply that manufacturers provide publishers with AWP’s and publishers report them. *See* AMCC ¶ 627. This does not meet the “ongoing organization” test of *Turkette*.

Second, plaintiffs fail to plead facts showing that the Manufacturer-Publisher Enterprises functioned as a continuing unit separate and apart from the pattern of racketeering activity. The alleged purpose of the enterprises is to publish false and fraudulent AWP’s, and to “deriv[e] profits from these activities.” AMCC ¶ 624. Thus, the purpose of the enterprises is the same as the pattern of racketeering activity, which is described as using interstate mail and wires to further the “AWP scheme” of “deliberately overstating the AWP’s,” thereby creating a “spread” to induce providers to purchase the manufacturers’ drugs, and thereby allowing the manufacturer to make more of a profit. *See* AMCC ¶¶ 637-41.

Finally, plaintiffs fail to plead facts to satisfy RICO’s requirement that the participants in the Manufacturer-Publisher Enterprises share a specific common purpose. *See, e.g., Blue Cross of Cal. v. SmithKline Beecham Clinical Labs, Inc.*, 62 F. Supp. 2d 544, 552 (D. Conn. 1998); *First Nationwide Bank v. Gelt Funding Corp.*, 820 F. Supp. 89, 98 (S.D.N.Y. 1993), *aff’d*, 27 F.3d 763 (2d Cir. 1994). Plaintiffs allege that the manufacturers’ AWP’s were “created solely to cause Plaintiffs and the Class members to overpay for drugs” and “to enable providers and others

to make secret profits through overcharges to patients, their insurers and other end payors,” resulting “in increased market share and profit for the Defendant Drug Manufacturers.” AMCC ¶ 3; *see also id.* ¶¶ 4-5. Plaintiffs offer no facts showing that the publishers share this common purpose. Rather, plaintiffs allege only that the publishers share the “common purpose of perpetuating use of AWP as a benchmark for reimbursement in the pharmaceutical industry.” AMCC ¶ 624. As this Court observed with respect to the MCC, “[t]here is no allegation that the publishing companies ever benefitted from the ‘spread’ scheme other than by the profits generated for publishing data provided to them.” *AWP Litigation*, 263 F. Supp. 2d at 185. The AMCC is no different. *See* AMCC ¶ 624.

Stripping away their conclusory allegations, plaintiffs have done nothing more than describe arm’s-length business arrangements between the defendant manufacturers and the publishing companies. A RICO enterprise cannot consist of merely two separate entities engaged in a common business venture. *See Feinstein*, 942 F.2d at 41 n.7 (banks and individuals engaged in the buying and selling of real estate did not constitute an enterprise) (citing *Turkette*, 452 U.S. at 583).<sup>11</sup> For these reasons, the alleged Manufacturer-Publisher Enterprises fail to meet the requirements of *Turkette*, and Count I should be dismissed.

**2. The Manufacturer-PBM Enterprises Are Deficient Because Plaintiffs Have Failed To Plead Facts Showing That They Constitute Ongoing Organizations Whose Members Function As Continuing Units And Share Common Purposes.**

In Count II, plaintiffs allege that each of the “Manufacturer-PBM Enterprises” is an

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<sup>11</sup> *See also Foval v. First Nat’l Bank of Commerce In New Orleans*, 841 F.2d 126, 129 (5<sup>th</sup> Cir. 1988) (plaintiff failed to allege an association-in-fact enterprise where “the evidence before the court establishe[d] only the existence of a commercial loan transaction”); *VanDenBroeck*, 210 F.3d at 700 (contractual arrangement between telemarketing company and its customers failed to present a viable RICO enterprise, and noting that evidence offered by plaintiff borrowers demonstrated nothing more than a business relationship).

ongoing and continuing business organization [whose members] are and have been associated for the common or shared purposes of selling, purchasing and administering AWPIDs to individual Plaintiffs and Class members . . . and deriving profits from these activities.

AMCC ¶ 652. Plaintiffs allege that the Manufacturer-PBM Enterprises each “had a common purpose of perpetuating use of AWPIDs as a benchmark for reimbursement in the pharmaceutical industry.” *Id.* ¶ 654. In other words, plaintiffs allege that there are 88 separate and distinct Manufacturer-PBM Enterprises operating in parallel, with the identical common purpose shared by each. *See* AMCC ¶ 661. Plaintiffs also allege that these enterprises each had a “systematic linkage” and a “common communication network.” *Id.* ¶ 653. As with the Manufacturer-Publisher Enterprises, the AMCC lacks any specific facts to support these averments. *See Feinstein*, 942 F.2d at 42, n. 7; *see also Goren*, 156 F.3d at 727.<sup>12</sup>

Like the enterprises described in Count I, the Manufacturer-PBM Enterprises fail to meet any of the requirements established by *Turkette*. Plaintiffs offer no facts to show that each manufacturer joined an identical but separate “ongoing organization” with each PBM, and that each PBM joined itself into an identical but separate “ongoing organization” with each manufacturer. While plaintiffs describe various business arrangements between manufacturers and PBMs, *see* AMCC ¶¶ 654, 657, they offer no facts to show that the separate parties to these arrangements merged into a separate “entity.” Similarly, plaintiffs present no facts to show that each manufacturer separately merged itself into a “continuing unit” with each PBM, or that each PBM separately did so with each manufacturer.

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<sup>12</sup> As in Count I, plaintiffs simply repeat conclusory allegations as to each of 22 manufacturers. *See* AMCC ¶ 661(a)-(v).

Finally, plaintiffs fail to plead facts showing that the participants in the Manufacturer-PBM Enterprises shared the “common purpose” required by *Turkette*. See pp. 16-17 *supra*. Plaintiffs allege only that the participants “had a common purpose of perpetuating use of AWP as a benchmark for reimbursement in the pharmaceutical industry.” AMCC ¶ 654. They provide not a single fact to support the conclusion that PBMs share this purpose. At most, plaintiffs allege nothing more than the existence of business arrangements between manufacturers and PBMs, which is insufficient to establish the existence of a RICO enterprise.

**B. Plaintiffs Fail To Plead Facts Showing That Defendants Conducted Or Participated In The Affairs Of The Alleged Enterprises.**

Even if plaintiffs allege a valid RICO enterprise (which they have not), they must set forth facts demonstrating that defendants conducted or participated in the affairs of the enterprise. 18 U.S.C. § 1962(c). In order to satisfy this element, plaintiffs must allege that defendants did something more than conduct their own affairs. *Arrandt v. Steiner Corp.*, No. 00 C 2317, 2001 WL 893807, at \*5 (N.D. Ill. Aug. 6, 2001).

Plaintiffs fail to allege any facts that satisfy this requirement. They allege that defendants conducted the affairs of the Manufacturer-Publisher Enterprises because each defendant (a) “directly controlled the price of its AWPIDs”; (b) “directly controlled the AWP that are reported by the Publishers”; (c) “directly controlled the creation and distribution of marketing, sales and other materials”; (d) used “a fraudulent scheme to manufacture, market and sell its AWPIDs on the basis of AWP” provided to the publishers; and (e) intended that each of the publishers would report the AWP. See AMCC ¶ 634. Plaintiffs make nearly identical allegations with respect to the Manufacturer-PBM Enterprises. See AMCC ¶ 667.

Fairly read, the AMCC alleges nothing more than actions by the manufacturers involving their own affairs. While they allege that “each of the Publishers has allowed these Defendants to exert control over their organizations,” AMCC ¶ 634(f), plaintiffs provide not a single fact to support this conclusion. And, while they allege that the defendants paid rebates to PBMs, *see* AMCC ¶ 667(f), they allege no facts showing how this amounted to control or participation in the Manufacturer-PBM enterprises. In sum, nothing in the AMCC indicates that a defendant drug manufacturer “directs the other members of the enterprise, takes orders from the other members, or controls the enterprise’s affairs in a way that is distinct from merely directing its own affairs.” *Arrandt*, 2001 WL 893807, at \*5.

Plaintiffs have not and cannot allege facts showing that the individual defendants each were able, separately but simultaneously, to direct the affairs of the various association-in-fact enterprises. By definition, merely alleging that a defendant directs its own affairs is insufficient to satisfy the “to conduct or participate” requirement of § 1962(c). With respect to the Manufacturer-Publisher Enterprises, plaintiffs would have to assert that each drug manufacturer simultaneously directed an employee of each publisher to take separate actions that are arguably inconsistent with one another, as the purpose of the alleged “scheme” was for each manufacturer to steal market share from its competitors (*i.e.*, its co-defendants). The same analysis would apply with regard to the Manufacturer-PBM Enterprises. As any such arrangement defies plausibility, the RICO claims in the AMCC should be dismissed.

**C. Plaintiffs Lack Standing To Assert Their RICO Claims Because They Cannot Show That Defendants Directly Caused Their Alleged Injuries.**

The civil enforcement section of RICO provides a cause of action for persons

injured in “their business or property *by reason of* a [RICO] violation.” 18 U.S.C. § 1964(c) (emphasis added); *see Sedima*, 473 U.S. at 496. It is not enough for the conduct at issue to be the “but for” cause of the injury; the violation must be the direct, proximate cause as well. *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *see also Carmelio v. American Fed’n*, 137 F.3d 666, 670 (1<sup>st</sup> Cir. 1998). For this reason, RICO plaintiffs may not recover if the causal connection is “too remote,” *Holmes*, 503 U.S. at 271; if the connection between the injury and the conduct is “insufficiently close,” *Carmelio*, 137 F.3d at 670; or if plaintiff’s loss was caused more directly by an intervening party, *Willis v. Lipton*, 947 F.2d 998, 1001 (1<sup>st</sup> Cir. 1991). Moreover, RICO claims cannot be founded on alleged misrepresentations when the plaintiff’s injury stems from the intervening acts of others.<sup>13</sup> Here, plaintiffs’ alleged RICO injury is that the prices they paid for defendants’ drugs were too high. However, the allegations of the AMCC reveal that plaintiffs’ alleged injuries were not caused directly by any actions of the defendants; rather, additional intervening acts break the causal chain of plaintiffs’ RICO claims.

Based upon the AMCC, it is clear that there are significant and multiple intervening acts between plaintiffs’ alleged injuries and the alleged acts of the defendants. First, plaintiffs do not allege that defendants made misrepresentations directly to them. Rather, they allege that the alleged misrepresentations were made to third-party publishers in the form of inflated AWP. AMCC ¶¶ 160-62, 172. Medicare and other payors, according to plaintiffs, relied on the

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<sup>13</sup> *See, e.g., Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 485 (D.N.J. 1998); *Barr Labs, Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 115-16 (E.D.N.Y. 1993); *Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp.*, 805 F. Supp. 1277, 1291 (D.S.C. 1992), *aff’d*, 998 F.2d 1009 (4<sup>th</sup> Cir.), *cert. denied*, 510 U.S. 993 (1993).

reported prices, which allegedly caused reimbursements and co-payments to be inflated, which in turn caused injury to plaintiffs.

Second, under Medicare, the prescribing doctor (or other providers), not defendant manufacturers, sets the charge for the drugs and submits claims for reimbursement to the Medicare carrier. AMCC ¶¶ 134, 148-149. The prescribing doctor may set her “actual charge” at any level, including a level below AWP. *See* 42 C.F.R. § 405.517(b) (setting total Medicare reimbursement as “the *lower* of the *actual charge* on the Medicare claims for benefits or 95% of the national average wholesale price”) (emphases added); *see also* AMCC ¶ 147. When the doctor charges less than 95% of AWP, the beneficiary pays a co-payment based on the doctor’s “actual charge,” not a higher co-payment amount based in any way on AWP. The provider’s charging decision is therefore a critical intervening cause of plaintiffs’ alleged injury.

Third, with respect to Medicare beneficiaries who are part of the AWP Payor Class, *see* AMCC ¶ 595, numerous government actors (and their agents), including Congress, CMS/HCFA, and the Medicare carriers that administer and process Part B claims, chose and continue to base drug reimbursement on AWP. Congress has always been free to base reimbursement on something other than AWP, as it has done with other federal programs. Further, Congress could have required no Medicare co-payment, or it could have required a flat fee rather than a percentage of total reimbursement. Moreover, from 1992 through 1997, HCFA had specific statutory authority to base reimbursement for Part B drugs on “Estimated Acquisition Cost,” but nevertheless chose to use AWP. *See* 42 C.F.R. § 405.517 (1992) (now superseded). And, it is the Medicare carriers that decide whether Part B claims submitted to them will be reimbursed. Simply put, members of the AWP Payor class who paid for Medicare Part B drugs paid an

amount that was determined exclusively by reference to the amount that the government and its agents have decided to pay for those drugs.

Fourth, with respect to the PBM Third-Party Payor Class, plaintiffs do not allege any facts that could support the conclusion that defendants were the cause of any injury flowing from the alleged Manufacturer-PBM Enterprises. The PBMs, not the defendants, contract with the plaintiff health plans. *See* AMCC ¶ 169 (“[H]ealth plans typically contract with intermediaries called pharmacy benefit managers (‘PBMs’) so that a health plan’s participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs.”). Defendants have no involvement in the contractual relationship between the health care plans and the third-party PBMs, and none is alleged. All that is alleged is that the PBMs use “inflated ‘Average Wholesale Price’ – or ‘AWP’” as the basis for reimbursement in arm’s-length contracts negotiated with third-party payor class members. *Id.* ¶ 171. The plaintiff health plans have unfettered discretion to base their payments to PBMs on any non-AWP benchmark. To the extent that they chose to base these payments on AWP, nothing in the AMCC implicates any defendant in any of their decisions to do so. Thus, any injury to plaintiffs arising from a PBM-health plan contractual relationship is not proximately caused by any actions on the part of defendants.

### **III. PLAINTIFFS FAIL TO STATE A CLAIM FOR CIVIL CONSPIRACY.**

The AMCC alleges, for the first time in this case, that each of 22 defendants (or defendant groups) engaged in separate civil conspiracies with each of the four major PBMs to